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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER

KISHORE, G

ART UNIT PAPER NUMBER

1615

10

DATE MAILED: 07/06/00

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 4-21-00

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 1-19 is/are pending in the application.  
Of the above, claim(s) 7-9, 11 & 18-19 is/are withdrawn from consideration.  
☐ Claim(s) is/are allowed.  
☒ Claim(s) 1-6, 10 & 12-17 is/are rejected.  
☐ Claim(s) is/are objected to.  
☐ Claim(s) are subject to restriction or election requirement.

#### Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on is ☐ approved ☐ disapproved.  
☐ The specification is objected to by the Examiner.  
☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.  
☐ received in Application No. (Series Code/Serial Number)  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received:

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☒ Notice of Reference Cited, PTO-892  
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).  
☐ Interview Summary, PTO-413  
☒ Notice of Draftsperson's Patent Drawing Review, PTO-948  
☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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### **DETAILED ACTION**

**The revocation of the power of attorney in paper No. 8, dated 6-14-00 is acknowledged.**

**1. Applicant's election without traverse of Group I and A, and SCRI as the species in Paper No. 7 is acknowledged.**

**Claims included in the prosecution are 1-6, 10 and 12-17.**

#### ***Claim Rejections - 35 U.S.C. § 112***

**2. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

**3. Claims 1-6, 10 and 12-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

**It is unclear as to what the side effects; also unclear is whether the side effects are because of the drug, solvent or the amphipathic molecule as recited in claims 1 and 12. 'including' is indefinite; the examiner suggests 'comprising' instead.**

**What is being conveyed by 'emulsifiers or detergent molecules there of' in claim 2? First of all, polyethoxylated oil itself is an emulsifier; secondly, applicant also recites 'derivatives' separately and that term includes even emulsifiers.**

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**The term, 'solvent' is generally used to denote the property that it is capable of dissolving the added compound. In instant claim 3, applicants recite hydrophilic solvent to dissolve the amphipathic compound; it is thus, improper.**

**The distinction between cremophor and cremophor EL as recited in claim 4 is unclear. Chemical names should be recited.**

**What is being conveyed through claim 5? Claim 1 recites solvent already for the drug; that means that the drug is soluble in that solvent. Why does it necessitates the addition of emulsifiers? Furthermore, if applicants' intent is to include an emulsifier, it should be stated so. 'necessitates' is not a positive expression.**

**Proper Markush language is 'selected from the group consisting of' (claim 6). The examiner suggests the deletion of 'products'.**

**What is being conveyed through claim 10? The administration of the complement activation inhibitor is not necessary in (I)? 'slowly' is a relative term.**

**What is meant by 'particulate biomaterials' which is recited as carrier in claim 14; similar is the case with 'emulsifier based drug vehicles'.**

***Claim Rejections - 35 U.S.C. § 103***

**4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

**(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior**

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**art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.**

**5. Claims 1-6, 10 and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ko (5,851,528) by itself or in combination with De Lacharriere (5,744,156).**

**Ko discloses a method of inhibiting complement activation by administering complement activation inhibitors. The method involves the administration of the inhibitor in controlled release delivery devices such as liposomes. The method is used for various conditions including the drug induced allergies and inflammation (note the abstract, col. 3, lines 49-52, col. 5, lines 32-51, col. 11, lines 1-42, examples and claims). Although Ko does not specifically teach the administration of the inhibitor together with the drug, it would have been obvious to one of ordinary skill in the art to administer together since Ko is suggestive of this combination from his statements on col. 10, line 42 et seq., according to which the inhibitor "can be combined with appropriate pharmaceutical formulation. An artisan would be motivated further to administer the drug or an agent which causes the side effects along with the inhibitor since the reference of De Lacharriere teaches such a concept; according to De Lacharriere hydroxy acids which cause side effects and the substance P antagonist which prevent these side effects are administered together. The criticality of cremophor (an amphiphilic compound) is unclear in the absence of unexpected results.**

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6. Claims 1-6, 10 and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ko (5,851,528) by itself or in combination with De Lacharriere (5,744,156), in further combination with applicant's statements of prior art.

Neither Ko nor De Lacharriere teach the use of cremophor as a drug or as a carrier. The references do not also teach that cremophors or liposomes cause compliment activation. Applicant on pages 5 and 6 cite various references which show that cremophors and liposomes cause compliment activation. Since the reference of Ko teaches that the inhibitors of complement activation for the treatment of conditions resulting from complement activation, it would have been obvious to one of ordinary skill in the art to use Ko's inhibitors for cremophor induced side effects since one would expect similar results irrespective of what causes the complement activation.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

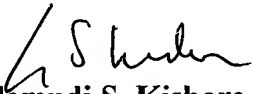
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

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**Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].**

**All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.**

**Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.**

  
**Gollamudi S. Kishore, Ph. D**

**Primary Examiner**

**Group 1600**

*gsk*

**July 3, 2000**